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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/966,581	09/28/2001	Sung-Kwon Jung	58378.124	4006
23483	7590	02/25/2004	EXAMINER	
HALE AND DORR, LLP 60 STATE STREET BOSTON, MA 02109			OLSEN, KAJ K	
			ART UNIT	PAPER NUMBER
			1753	

DATE MAILED: 02/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/966,581

Applicant(s)

JUNG ET AL.

Examiner

Kaj Olsen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 20-35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 20-35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

2. Claims 20, 21, 23, 24, 27-33, and 35 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Jung et al (Anal. Chem. 2001, 73, pp. 3759-3767). The American Chemical Society indicates that this article was published on-line on 6/30/2001 and thereby qualifies as prior art under 35 U.S.C. 102(a).

3. The subject matter of Jung substantially overlaps the subject matter of the present invention (e.g. fig. 1-7 of Jung appear to be almost identical to fig. 1-7 of the present invention).

4. In response, applicant has filed a declaration under 37 C.F.R. 1.132 establishing that James Trimarchi was a co-author of the Jung reference, but is not a co-inventor of the instant invention because he did not make an inventive contribution to the subject matter. This declaration is persuasive. However, this declaration alone cannot overcome the rejection under 35 U.S.C. 102(a) because, even absent the issues related to Mr. Trimarchi, the inventorship still differs from that of the Jung reference in that only three of the four inventors were listed on Jung reference. Mr. Pepperell is listed as a co-inventor of the instant invention even though he was not considered to be an author of the Jung reference, which was a reference that clearly anticipated most of the claims. As long as the inventorship differs from the authorship of the clearly anticipating Jung reference (with the exception of issues concerning Mr. Trimarchi which

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have been settled), Jung will still be the work of "others" and will continue to qualify as prior art under 35 U.S.C. 102(a) (see MPEP 2132, roman number III).

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 22 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jung in view of Pritchard et al (USP 5,762,770).

8. Jung set forth all the limitations of the claim, but did not explicitly recite the use of either dehydrogenase or of lactate oxidase. Pritchard teaches in an alternate biosensor that glucose dehydrogenase can also be utilized for the detection glucose (see table 1). Table 1 also shows that a given biosensor can be modified to measure other analytes such as lactose using lactate oxidase. It would have been obvious to one of ordinary skill in the art at the time the invention

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was being made to utilize the dehydrogenase teaching of Pritchard for the method of Jung because the substitution of one known enzyme for another known enzyme requires only routine skill in the art. In addition, it would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the lactose teaching of Pritchard for the method of Jung in order to extend the utility of the flux sensor to other art recognized bioanalytes.

9. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jung in view of Spring et al (USP 5,643,721).

10. Jung set forth all the limitations of the claim, but did not explicitly recite the use of glutamate oxidase as the enzyme. Spring teaches in an alternate biosensor that sensors suitable for monitoring glucose can also be modified to sense glutamate by use of glutamate oxidase (see example 7 starting at col. 23). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Spring for the method of Jung in order to extend the utility of the flux sensor to other art recognized bioanalytes.

11. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jung in view of Keefe et al (USP 6,062,225).

12. Jung set forth all the limitations of the claim (see rejection above), but did not explicitly recite the use of the sensor for the determination of embryo viability (see 112 rejection above). Keefe discloses that analyte flux measurements may be utilized to determine if the embryos are morphologically capable of cleavage (col. 1, line 52 through col. 2, line 19). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Keefe for the method of Jung in order to assist a medical practitioner in determining the relative health of a developing fetus.

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***Response to Arguments***

13. Applicant's arguments concerning the rejection under 112 were persuasive and the examiner is withdrawing that rejection. The examiner response to the filed Declaration can be in the rejection under 102(a) above.

***Conclusion***

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kaj Olsen whose telephone number is (571) 272-1344. The examiner can normally be reached on Monday through Thursday from 7:00 A.M. to 4:30 P.M. and on alternate Fridays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen, can be reached on 571-272-1342. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Kaj Olsen', with a stylized flourish extending to the right.

Kaj Olsen Ph.D.  
Primary Examiner  
AU 1753  
February 19, 2004